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DEC 04 2009

In re Application of:
JONES et al.

Serial No.: 10/541,657

Filed: March 3, 2006

Attorney Docket No.: 34.US5.PCT

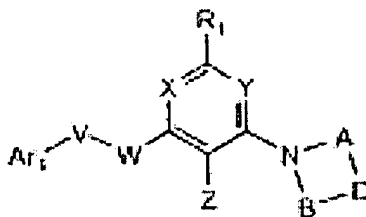
Title: **1,2,3-TRISUBSTITUTED ARYL AND
HETEROARYL DERIVATIVES AS
MODULATORS OF METABOLISM
AND THE PROPHYLAXIS AND
TREATMENT OF DISORDERS
RELATED THERETO SUCH AS
DIABETES AND HYPERGLYCEMIA**

DECISION ON PETITION

This letter is in response to the Petition under 37 C.F.R. 1.144 filed on June 9, 2009.

BACKGROUND

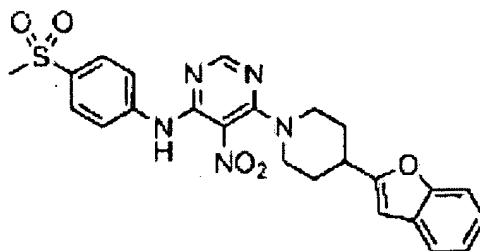
On June 11, 2008 the examiner set forth a restriction requirement separating claims 1-85, 87-92 and 100 into eighteen groups.



Groups I to XIII related to the structure shown above and concerned choices of X, Y Ar₁, W, V, A, B and D. Groups XIV-XVIII concerned methods of using and methods of making the compounds having the structure shown above. The examiner asserted that "Groups I-XIII are directed to structurally dissimilar compounds such that the variable core created by varying the definitions of the Formula do not belong to a recognized class of chemical compounds in the art and references that exist in anticipating one invention would not render obvious the others."

The examiner required a further election of species from those presented in claims 73-76.

Applicants elected Group V and the species shown below with traverse in the Paper filed December 19, 2008.



Applicant's traversed by asserting that the common features of the compounds constituted a special technical feature and that" the International Searching Authority found the claims of the present application meet the requirement of unity of invention. (page 8)"

Applicant further urged that the method of use/making claims had unity of invention based on the premise that the compound claims had unity of invention.

Applicant further argued that even if lack of unity were established that the groups from which election was required are arbitrary and improper.

The restriction requirement, however, does not appear to consider the definitions in the *claims* of the application, as is required for properly making a restriction requirement. It is not seen from where in the claims the Examiner has derived the various definitions used to define the claims. For example, Ar₁ in the claims is not limited to phenyl or pyrazole. Further, with regard to the applicants' elected group, Group V, the applicants do not see a definition in the claims where "A, B, and D form a 6-membered ring."

Applicant alleged that the restriction requirement "abridges the applicants' right to claim the generic subject matter which the applicants regard as their invention" and "the arbitrary definitions of the groups would deprive the applicants of their right to claim the entirety of their invention."

Applicant alleged the "even if a lack of unity were established, the arbitrary definitions of the groups would limit applicants' invention more than could conceivably be required to restore unity of invention."

Applicant alleged that no search burden existed as the International Searching Authority "performed a complete search with respect to the claimed invention."

Applicant alleged that the restriction requirement was incomplete because Group XIII was a "catch-all" group.

Applicant alleged that the restriction requirement lacked clarity because it failed to properly set forth which claims were properly in Groups I-XIII.

Applicant alleged that claims 1 and 78 were linking claims as per MPEP 809.03.

The Examiner issued an Office Action on March 9, 2009 in which the restriction requirement was made final. The Examiner alleged:

The only common portion of ALL the compounds encompassed by the scope of these claims is the central ring, which at best can be a pyrimidine, pyridine or phenyl ring according to the claim set, therefore no unity of invention exists. Examiner asserts that a special technical feature is exactly that, "special." Any position where multiple variables may exist, such as X, Y, Ar1, the N-A-B-D ring, Z and R1, then those positions cannot be considered "a special technical feature" if those positions can be represented by multiple different groups in the compound. For a prior art example which reads on the claims and thus breaks the unity of invention please see the 102(b) rejection cited below.

Applicants have additionally argued that if the special technical feature is not present, and hence there is no unity of invention, that the examiner did not properly restrict the claims. Examiner points to the restriction requirement and notes that there are groups for every possible scenario of compound for the claims set forth in the claim set. Applicants also argue that the restriction requirement abridges their right to claim the generic subject matter. Applicant is correct. This is because the generic subject matter was deemed to be multiple inventions. Applicants may not claim subject matter so generic that it results in multiple patentable inventions.

Finally, as a matter of form, examiner would like to remind applicants that the election of a species is merely to denote a starting point in the examiner's search. Should the elected species be found allowable, the examiner would then move on to other species within the broader genus, the applicants are not being restricted to a single compound for patentability.

DISCUSSION

The examiner's initial assertion that unity of invention was lacking appears to most closely track PCT/GL/ISPE/1 Chapter 10 Unity of Invention 10.44 Example 24

Claim 1: A pharmaceutical compound of the formula:

A – B – C – D – E

wherein:

A is selected from C₁-C₁₀ alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C₅-C₇ heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C₁-C₆ alkyl or alkenyl or alkynyl, amino, sulfoxy, C₃-C₈ ether or thioether;

C is selected from C₅-C₈ saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

*D is selected from B or a C4-C8 carboxylic acid ester or amide; and
E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl,
pyridyl, or oxazolyl.*

From the above formula no significant structural element can be readily ascertained and thus no special technical feature can be determined. Lack of unity exists between all of the various combinations. The first claimed invention would be considered to encompass the first mentioned structure for each variable, that is, A is C₁ alkyl, B is C₁ alkyl, C is a C₅ saturated heterocycle having one O heteroatom, D is C₁ alkyl, and E is a substituted phenyl.

However, it appears that the examiner departed from the example in not setting forth the groups as per the example. This is apparent since if one were to follow the guidelines the first group would have been A= methylene, B=methylene, D=O, V=methylene, W=NR₄, X=N, Y=N, Z=C₁ acyl, Ar₁= aryl, and R₁=H. Additional groups would then reflect combinations of each of the recited possibilities. Considering just the possibilities for A, B, D, V, W, X and Y, Z and R₁ would result in (3)(3)(6)(4) (6) (2)(2)(2)(1)= 10,368 groups without taking into account the suggested substitutions and treating Z as though it had only two possibilities.

The examiner appears to have taken a more liberal approach toward claim by setting forth groups which he considered to be sufficiently related so as to have a unifying feature which may or may not also be a special technical feature. The difficulty with such an approach is that it may result in groups for which no written description exists in the claims or specification as originally filed. An additional difficulty in the examiner's grouping is the failure to address either the R₁ or Z substituents.

When the independent claim lacks unity of invention it is incumbent upon the examiner to analyze the dependant claims for a special technical feature and to group those having the same special technical feature. The groupings set forth by the examiner do not appear to reflect such an analysis as each of groups I-XIII refers to claims 1-78 whereas they should refer to subsets thereof based on the limitations recited in claims 2-78.

As noted above applicant elected Group V and an individual compound from those listed in claims 73-76 (B125) and presented extensive arguments as to why unity of invention was present.

However, it is noted that nowhere in applicant's 18 pages of argument is the examiner's failure to address either the R₁ or Z substituents specifically set forth.

Applicant's argument that neither the ISA nor the IPRP indicated lack of unity is not persuasive since it is not a requirement that lack of unity be made if unity of invention is not present nor is the USPTO bound by the determination of either the ISA or IPRP. It is further noted that the IPRP does not appear to have been submitted for the examiner's consideration.

Applicant's allegation that no search burden is present is unpersuasive as search burden is not the criteria for lack of unity.

In the Office Action of March 9, 2009 the examiner found none of applicant's arguments persuasive. The examiner presented a line of argument consistent with Example 24 and in addition rejected claims 1-3, 9, 12, 14-17, 32, 39, 41, 42 and 70 as anticipated by Cocco et al. (2000) thereby establishing that the claims lacked unity of invention.

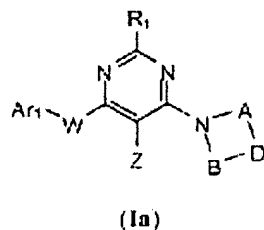
The examiner's remarks concerning the election of species are not on point as they are not consonant with unity of invention.

On June 9, 2009 applicant filed an Amendment accompanied by the instant petition. Claim 1 is substantively amended and limited to a subgenus of original claim 1. In the amendment the structure shown above is depicted, however, among the amendments to claim 1 is the elimination of V.

In response to the Office Action of March 9, 2009 applicants substantively amended the claims and filed the instant petition.

The amendment to claim 1 eliminating V from the structural formula appears to reflect applicant's recognition that the prior art anticipated at least claim 1. Therefore, claim 1 as originally presented lacked unity of invention.

At page 7 of the instant petition applicant alleges that the genus of compounds having the following structure



wherein:

- A and B are C1-3 alkylene which substituted with 1 to 4 methyl groups;
- D is CR₂R₃ or N-R₂;
- W is NR₄ or O (where R₄ is H or alkyl); and
- R₁ and Z are selected from a limited number of substituent options[.]

has unity of invention.

To the extent that the previously applied prior art no longer anticipates certain of the claims applicant is correct. However, whether or not the amended claims have unity of invention has not yet been determined.

Applicant further argues that the method of use claims share unity of invention based on the Administrative Instructions. Applicant argues that if the independent claims avoid the prior art that no problem of unity of invention arises with respect to claims which depend from the independent claim and that unity is apparent because claims 1-78 and claims 79-85, 87-92 and 100 are related as product and methods of using that product.

It is noted that claim 100 is actually a method of making a pharmaceutical composition comprising the compound having the recited structure. In addition method claims 79 and 82-84, are independent claims. To the extent that such method claims do not share a special technical feature with each other and in accordance with 37 CFR §1.475(d) they may lack unity of invention.

Applicant reiterates his previous arguments that the “groups from which election was required were based on arbitrary definitions and improper.

Applicant argues that the definitions of the groups provided by the examiner are “artificial definitions different from those found in the claims.”

Applicant argues that “the restriction requirement, by imposing arbitrary definitions on the groups would abridge the applicants right to claim the generic subject matter which the applicants regard as their invention,” “the arbitrary definitions of the groups would deprive the applicants of their right to claim the entirety of their invention,” “even if lack of unity of invention were established, the arbitrary definitions of the groups would limit applicant’s invention more than could conceivably be required to restore unity of invention.”

Applicant’s arguments have been fully considered, however, given the determination that claim 1 lacked unity of invention the examiner attempted to set forth groupings which contained related compounds. Such groupings necessarily reflect the examiner’s understanding of the invention and may not be consonant with applicant’s view as is apparent from applicant’s argument concerning the difference in definitions. But, the lack of unity in claim 1 necessitates a redefinition of the claim. The examiner met his burden whereas applicant in his initial response did not propose new definitions. It is noted that in the amendment of June 9, 2009 that applicant has redefined his invention. Applicant could have proposed alternatives to the examiner’s groupings which he felt were consonant with his view of the invention and which, in addition, took into account the findings of the ISA as well as the prior art submitted with the IDS of March 1, 2007.

In the claims as originally filed claims 2-8 were directed to limitations regarding W, claims 8-11 were directed to limitations regarding V, claims 12-14 were directed to limitations regarding A and B, claims 15-21, 23-38 were directed to limitations regarding D, claim 39 was directed to limitations regarding Z, claim 40 was directed to limitations regarding R₁, claims 42-66 were directed to limitations regarding Ar₁, and claims 67-72 were directed to limitations regarding X and Y. As the claims were originally drafted the only independent compound claim was claim 1.

PCT/GL/ISPE/1 Chapter 10 Unity of Invention 10.08 states:

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity *a posteriori* (that is, arising only after assessment of the prior art) may be raised. Similar

considerations apply in the case of a genus/species or combination/subcombination situation. This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.

The examiner appears to have taken this approach. The examiner considered the ring containing X and Y and on this basis proposed groups I-XII where X and Y are both N and group XIII which included all other X and Y combinations. However, to have been complete the examiner should have proposed groups for each of the X,Y combinations set forth in claims 67-69 and 71 and 72. For each X, Y group the examiner then presented choices for the ring structure containing A, B and D. The examiner did not present a rationale for his grouping of A, B and D together nor the limitation to 5 and 6 membered rings, however, it would appear to arise from a consideration of the claims and the compounds synthesized. The examiner then presented a restricted set of choices for V and W as well as Ar₁. Groups I-XII do not cover all the possible combinations presented by applicant's claims. The examiner set forth Group XIII to embrace those combinations of X, Y, (A,B,D), V and W, and Ar₁ not explicitly recited in Groups I-XII. Applicant has disparaged Group XIII as a catch-all group. It would appear that Group XIII is more extensive than Groups I-XII, however, it is only necessary that it not share unity of invention with Groups I-XII and it does not appear to do so.

Applicant further argues "the examiner failed to make a showing that applicants claimed invention would impose a serious undue burden," the restriction requirement is incomplete, and the restriction requirement lacks clarity. Applicant states "[t]he restriction requirement also ignores the fact that there are linking claims present in the application."

Applicant's arguments relating to search burden and linking claims are directed to requirements for restriction under US restriction practice, however, the instant application is subject to Unity of Invention practice.

Applicant's assertion that the restriction requirement is incomplete stems from his reasoning that Groups I-XII do not cover all the subject matter of claim 1 and that the examiner recognized this to be the inclusion of Group XIII. Applicant urges that Group XIII is improper as it is not based on the claimed subject matter and applicant's claims do not include any such definition of the subject matter as set forth in Group XIII. First, Groups I-XIII do appear to include all the subject matter of claim 1. Second, applicant has not demonstrated that there exists a combination of applicant's original claims which would fall outside of Groups I-XII and not be present in Group XIII. It would appear to be applicant's position that the examiner did not set forth a sufficient number of groups. As noted above an exhaustive recitation of the inventions in relation to the possibilities for A, B, D, V, W, X and Y Z and R₁ would result in (3)(3)(6)(4) (6) (2)(2)(2)(1)=10,368 groups without taking into account the suggested substitutions. The restriction requirement and the examiner's response to applicant's initial traversal could have provided more explanation, however, neither is so deficient as to have precluded applicant's making a rational election.

Applicant urges that the objection to claims 1-78 as containing non-elected subject matter is improper for the same reasons the restriction requirement is improper. Applicant further argues that MPEP 803.02 and 809 should apply to the instant claims.

Thus, if the restriction requirement were proper then the objection would be proper. MPEP 803.02 and 809 are directed to US restriction practice.

A consideration of the claims as originally filed suggests the following analysis with respect to lack of unity of invention.

- A. Claims 1, 2-8 wherein a choice of W is made.
- B. Claims 1, 8-11 wherein a choice of V is made.
- C. Claims 1, 12-14 wherein choices for A and B are made.
- D. Claims 1, 15-38 wherein choices for D are made.
- E. Claims 1, 39 and 40 wherein choices for Z are made.
- F. Claims 1 and 41 wherein a choice is made for R₁.
- G. Claims 1, 42-66 wherein a choice of Ar₁ is made.
- H. Claims 1 and 67-72 wherein a choice for X and Y is made.

Each group would represent a combination of one of A-H. A choice within each of A-H would be required. Within D and G further groups could arise depending upon whether the differences in structure retain unity of invention.

With regard to claims 73-77 the individual compounds therein would be grouped with whichever combination of A-H was elected. An election of a specific species would be required if the related compounds did not have unity of invention.

Applicant's amendment of the claims suggests that an analysis with respect to unity of invention should include:

- A. Claims 1, 2-5 wherein a choice of W is made.
- B. Claims 1, 12-14 wherein choices for A and B are made.
- D. Claims 1, 16-38 wherein choices for D are made.
- E. Claims 1, 39 and 40 wherein choices for Z are made.
- F. Claims 1 and 41 wherein a choice is made for R₁.
- G. Claims 1, 42-66 wherein a choice of Ar₁ is made.

Election of Species

The examiner required an election of species as part of the original lack of unity, however, the examiner appears to have done so relying on US Markush practice and not in accordance with MPEP 1893.03(d).

Applicant traversed the election by citing to *Caterpillar Tractor Co. v. Com'r Pat. & Trademarks*, 650 F. Supp. 218 (E.D. Va. 1986) as directing the Office to follow the P.C.T. rules with respect to unity of invention.

In the Office Action of March 9, 2009 the examiner responded to applicant's traversal by stating that the election of species was solely for search purposes and that if the elected species was found allowable the examiner would move to other species. The examiner again treats the election of species according to US restriction practice and not in accordance with MPEP 1893.03(d). The examiner presented no prior art based rejection of the elected species nor for any additional species within the elected group. The examiner's rejection of the claims under 35 USC §112 first paragraph indicates that the examiner considers that the elected group is enabled.

DECISION

The election of species was improper to the extent that it did not follow the procedure set forth in MPEP 1893.03(d). Upon resuming prosecution the examiner is directed to evaluate all the pending claims in accordance with the procedures set forth in MPEP 1893.03(d).


Despite the errors in the holding of lack of unity the evidence of record clearly indicates that the claims as originally filed did not have unity of invention. The examiner's failure to discuss the claims with regard to the Z and R₁ substituents is in error. Applicant's amendments of the claims accompanying this petition have significantly modified the genus of compounds claimed.

Upon resuming prosecution the examiner is directed to evaluate the amended claims to determine if they have unity of invention and if the amendments are consonant with the elected invention. Should the examiner determine that the amend claims lack unity of invention he should so notify applicant prior to proceeding further in the examination of the claims. With respect to the method claims the examiner is advised to consider whether or not the method claims currently pending have unity of invention with the claimed compounds.

The objection to claims 1-78 is improper despite the restriction requirement being proper as no applicable statute or rule permits such an objection.

The petition is **GRANTED-IN-PART** for the reasons set forth above.

Should there be any questions about this decision, please contact Quality Assurance Specialist Michael P. Woodward, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-8373 or by facsimile sent to the general Office facsimile number, 571-273-8300.


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Director, Technology Center 1600